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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,314	05/17/2005	David Wallach	WALLACH33	6672

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EXAMINER	
SWOPE, SHERIDAN	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,314	WALLACH ET AL.	
	Examiner	Art Unit	
	SHERIDAN SWOPE	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *106-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *106-111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Request for Continued Examination of July 6, 2010, in response to the action mailed January 5, 2010, is acknowledged. It is acknowledged that all prior claims have been cancelled and Claims 106-111 have been added. Claims 106-111 are pending and are hereby considered. It is noted that Applicants have changed the recited invention from a method for treatment of rheumatoid arthritis, a disease involving IL-2, using the NIK polypeptide of SEQ ID NO: 18 to an isolated NF-κB inducing kinase (NIK) polypeptide that binds to a common gamma chain (cgc). Nonetheless, in the interest of public service, Applicants related, but distinct, newly recited invention is herein examined.

Priority

The priority date granted for the instant claims is April 15, 2003, the filing date of PCT/IL03/00317, which disclosed the elected invention. The Examiner fails to see that Israel 14927 and 152183 disclose both of SEQ ID NO: 18 and 19.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

> The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

> A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

> An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 106-108 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 8 of US Application 12/166,110. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 106-108 herein and Claim 8 of 12/166,110 are both directed to peptides that bind to cgc. The claims differ in that Claim 8 of 12/166,110 encompasses any peptide that inhibits binding between NIK and cgc, while Claims 106-108 encompass fragments of SEQ ID NO: 18 or 19 that bind cgc. The portion of the specification in 12/166,110 that supports the recited methods includes embodiments that would anticipate Claims 106-108 herein, e.g., fragments of SEQ ID NO: 18 or 19 that bind cgc, which are also peptides encompassed by in Claim 8 of 12/166,110. Claims 106-108 herein cannot be considered patentably distinct over Claim 8 of 12/166,110 when there are encompassed embodiments (fragments of SEQ ID NO: 18 or 19 that bind cgc) that would anticipate Claims 106-108 herein. Alternatively, Claims 106-108 herein cannot be considered patentably distinct over Claim 8 of 12/166,110 when there are specifically disclosed embodiments in 12/166,110 that supports Claim 8 of that patent and falls within the scope of Claims 106-108 herein, because it would have been obvious to a skilled artisan to modify the peptids of Claim 8 of 12/166,110 by selecting specifically disclosed embodiment that supports those claims, i.e., peptide that inhibits binding between NIK and cgc, wherein the peptide binds to cgc, as disclosed in 12/166,110. One having ordinary skill in the art would have been motivated to do this, because such an embodiment, is disclosed as being a preferred embodiment

within the other application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 106-111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claim 106(c) and Claim 107(c), the phrase "residues 640 to 720 of SEQ ID NO: 19" renders the claim indefinite because SEQ ID NO: 19 has only 324 residues. The skilled artisan would not know the metes and bounds of the recited invention. Claims 109 and 111, as dependent from Claim 106, are indefinite for the same reason. Claim 106(c) and Claim 107(c) are so unclear as to prohibit searching the recited sequences.

For Claims 106(d), 107(d), and 108(d), the phrase "the carboxyl group" renders the claim indefinite. It is unclear whether said phrase means only the C-terminal carboxyl group or any carboxyl group. The skilled artisan would not know the metes and bounds of the recited invention. Claims 109-111, as dependent from Claim 106, 107, or 108, are indefinite for the same reason. For purposes of examination, it is assumed that "the carboxyl group" means any carboxyl group.

For Claim 111, the phase "860 of human NIK", without reference to a specific sequence, renders the claim indefinite. The skilled artisan would not know the metes and bounds of the recited invention. Claim 111 is so unclear as to prohibit searching the recited sequence.

Any subsequent rejection based, on clarification of the above phrases and terms, will not be considered a new ground for rejection.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 106-108 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptides of SEQ ID NO: 18 and 19, which bind to a human bone marrow cgc protein, does not reasonably provide enablement for any fragment or variant, of any polypeptide comprising or consisting of SEQ ID NO: 18 or 19, that bind to any cgc protein having any structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill

of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claim 106 is so broad as to encompass any fragment or variant of any polypeptide comprising SEQ ID NO: 19 that binds to any cgc protein having any structure. Claim 107 is so broad as to encompass any fragment or variant of SEQ ID NO: 19, or fragment of said variants, that binds to any cgc protein having any structure. Claim 108 is so broad as to encompass any fragment or variant of SEQ ID NO: 18, or fragment of said variants, that binds to any cgc protein having any structure. It is noted that by use of "comprising" language and encompassing any fragment of the encompassed variants, Claim 106-108 encompasses polypeptides, wherein the activity is not derived from the sequence homologous to SEQ ID NO: 18 or 19.

The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claim. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired binding to any cgc protein having any structure requires a knowledge of and guidance with regard to which amino acids in the polypeptides' sequences, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the polypeptides of SEQ ID NO: 18 and 19.

While recombinant and mutagenesis techniques as well as binding assays are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims. Furthermore, the positions within a protein's sequence where

amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable (Galye et al, 1993; Whisstock et al, 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of Claim 106, which encompasses all fragments and variants of any polypeptide comprising SEQ ID NO: 19 that bind to any cgc protein having any structure. The specification does not support the broad scope of Claim 107, which encompasses all fragments and variants of SEQ ID NO: 19, or fragment of said variants, that bind to any cgc protein having any structure. The specification does not support the broad scope of Claim 108, which encompasses all fragments and variants of SEQ ID NO: 18, or fragment of said variants, that bind to any cgc protein having any structure. The specification does not support the broad scope of Claims 106-108 because the specification does not establish: (A) the structure of polypeptides having any cgc function, as encompassed by the claims; (B) any fragment or variant of (i) any polypeptide comprising SEQ ID NO: 19 or variant thereof, (ii) the polypeptide of SEQ ID NO: 19 or variant thereof, or (iii) the polypeptide of SEQ ID NO: 18 or variant thereof that binds to any cgc protein having any structure; (C) regions of each protein's structure which may be modified without affecting the desired activity; (D) the general tolerance of the desired activities to modification and extent of such tolerance; (E) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (F) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of any fragments or variants, of any polypeptide comprising or consisting of SEQ ID NO: 18 or 19, that bind to any cgc protein having any structure. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of polypeptides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

It is suggested that Applicants' representative contact the Examiner to discuss this rejection.

Written Description

Claims 106-108 are rejected under 35 U.S.C. 112, first paragraph/written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of fragments and variants, of any polypeptide comprising or consisting of SEQ ID NO: 18, SEQ ID NO: 19, or variants or fragments thereof, that bind to any cgc protein having any structure. The specification teaches the structure of no representative species of such fragments and variants. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of binding to any cgc protein having any

structure. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

It is suggested that Applicants' representative contact the Examiner to discuss this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 106, 107, and 109 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallach et al, 1997 (IDS; WO9737016). Wallach et al teaches human NIK as well as the fragment of human NIK set forth by SEQ ID NO: 19 (Example 5). Therefore, Claims 106, 107, and 109 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallach et al, 1997.

Allowable Subject Matter

No claims are allowable.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate

pages. It is also requested that the serial number of the application be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652